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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/863,125	05/22/2001	Elizabeth S. Light	112/002/CON1	9583

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EXAMINER

CHAKRABARTI, ARUN K

ART UNIT PAPER NUMBER

1634

DATE MAILED: 04/12/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/863,125

Applicant(s)

Light

Examiner

Arun Chakrabarti

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 5/22/01, 8/2/01, and 10/09/01.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 25 and 26 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 25 and 26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 20) ☐ Other: _____

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DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 20-24, drawn to a composition comprising a target nucleic acid, classified in class 536, subclass 22.1+.
 - II. Claims 25-26, drawn to method of detecting a target nucleic acid sequence, classified in class 435, subclass 6.
2. The inventions are distinct, each from the other because of the following reasons:

Inventions in Group I and Group II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the method of detecting a target nucleic acid of Group II can be practiced by the composition of Group I or by PCR, hybridization with a synthesized oligonucleotide or by a gene sequencer.
3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

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4. During a telephone conversation with Huw Jones on November 15, 2001 a provisional election was made with traverse to prosecute the invention of Group II, claims 25-26.

Affirmation of this election must be made by applicant in replying to this Office action. Claims 20-24 are withdrawn from further consideration by the examiner, 37 CAR 1.142(b), as being drawn to a non-elected invention.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CAR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CAR 1.48(b) and by the fee required under 37 CAR 1.17(I).

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 25-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 25, the phrase "one can determine" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. The

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metes and bounds of the claims are vague and indefinite. It is suggested to change the phrase to "determinable".

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claim 25 is rejected under 35 U.S.C. 102 (b) as being anticipated by Singer et al. (U.S. Patent 5,523,204) (June 4, 1996).

Singer et al. teach a method of detecting a target nucleic acid sequence in at least one cell comprising observing the location of a product of an enzyme and a chromogen composition, the product being individually associated with each of at least one of the target nucleic acid sequences and each of the target nucleic acid sequences associated with the product is separate from each other such that the product is distinguishable from the product associated with other copies of the target nucleic acid sequences in the same cell such that one can determine the number of original copies of the target nucleic acid sequences in the at least one cell (Example 2, column 14, line 25 to column 15, line 33 and column 8, line 37 to column 9, line 15 and Figures 1a and 1b and Column 3, lines 15-37).

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Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 25-26 are rejected under 35 U.S.C. 103(a) over Singer et al. (U.S. Patent 5,523,204) (June 4, 1996) in view of Duhamel et al. (U.S. Patent 6,068,843) (May 30, 2000).

Singer et al teach the method of claim 25 as described above.

Singer et al do not teach the method, wherein the product is located at the target nucleic acid sequence of chromosomal DNA exclusively.

Duhamel et al. teach the method, wherein the product is located at the target nucleic acid sequence of chromosomal DNA exclusively (Abstract and Column 7, lines 3-16).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to combine and substitute the method, wherein the product is located at the target nucleic acid sequence of chromosomal DNA exclusively of Duhamel et al. in the detection of nucleic acids in cells by chromogenic method of Singer et al. since Duhamel et al. state, "The probes and primers can preferably hybridize to all serotypes of *S. hyodysenteriae* and not other closely related microorganisms. The target sequence is preferably about a 2.3 kb

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fragment of *S. hyodysenteriae* chromosomal DNA. The primers and probes can be used in methods and kits for detecting *S. hyodysenteriae* in a biological sample, preferably by detecting amplification products using primers that hybridize to the target sequence (Column 7, lines 8-16).” Moreover, Singer et al provides further motivation as Singer et al state, “In situ methods of nucleic acid analysis allow detection and localization of specific nucleic acid sequences within morphologically intact cells (Column 3, lines 15-17)”. By using these strong motivations as well as scientific reasoning, one ordinary practitioner would have combined and substituted the method, wherein the product is located at the target nucleic acid sequence of chromosomal DNA exclusively of Duhamel et al. in the detection of nucleic acids in cells by chromogenic method of Singer et al. to improve the detection and localization of specific nucleic acid sequences within morphologically intact cells. An ordinary practitioner would have been motivated to combine and substitute the method, wherein the product is located at the target nucleic acid sequence of chromosomal DNA exclusively of Duhamel et al. in the detection of nucleic acids in cells by chromogenic method of Singer et al. in order to achieve the express advantage, as noted by Duhamel et al, of the method which provides primers and probes to detect a specific chromosomal DNA preferably and also in order to achieve the express advantages, as noted by Singer et al of a method which allows detection and localization of specific nucleic acid sequences within morphologically intact cells.

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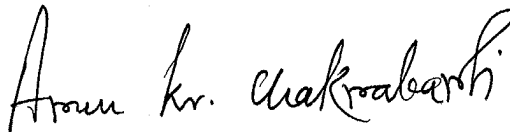
Conclusion

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arun Chakrabarti, Ph.D. whose telephone number is (703) 306-5818.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703)308-1152.

Any inquiry of general nature or relating to the status of this application should be directed to the Technology Center receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission via the P.T.O. fax Center located in Crystal Mall 1. The CM1 Fax Center numbers for Technology Center 1600 are either (703) 305-3014 or (703) 308-4242. Please note that the faxing of such papers must conform with the Notice to comply published in the Official Gazette, 1096 OG 30 (November 15, 1989).



Arun Chakrabarti,

Patent Examiner

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November 19, 2001